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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/502,409 | 07/23/2004 | Yoshiharu Uchata | 10921.235USWO | 3948 |
| 7590 Douglas P Mueller Merchant & Gould 3200 IDS Center 80 South 8th Street Minneapolis, MN 55402-2215 | | | EXAMINER REYNOLDS, STEVEN ALAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3728 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/502,409

Applicant(s)

UEHATA, YOSHIHARU

Examiner

Steven Reynolds

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/23/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Preliminary Note

1. In the rejections below, the “analyzer” and “sampling tool” are treated as elements within functional and intended use languages, not positive elements.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckstein et al. (US 3,917,456). Regarding claims 1-5, Eckstein et al. discloses a kit holding adapter capable of holding an analyzer together with a sampling tool; a first holding portion (inside of bag 2) capable of holding an analyzer and a second holding portion (inside surface of portion 7) capable of holding a sampling tool; the first holding portion includes an opening (opening in bag) capable of partly exposing an analyzer; the first holding portion and the second holding portion are separated by a partition wall (surface of bag 2), the partition wall being formed with a cutout (opening in top of bag 2) which conducting an inside of the first holding portion with an inside of the second holding portion; and the first and second holding portions are integrally formed as one piece.

Regarding claims 6-10, Eckstein et al. discloses a main body (portion 7) capable of holding an analyzer and a sampling tool; and an article holding portion (portion 6) capable of containing articles used for at least one of an analyzer and a sampling tool, or other items used in conjunction with the sample analysis or the sampling; the main body includes the first holding portion capable of holding an analyzer and the second holding portion capable of holding a sampling tool; the article holding portion includes a plurality of containing rooms (compartments 15 in portion 6); the article holding portion is removably attached to the main body (when hinge 8 is removed); and the article holding portion is integrally formed with the body as one piece (with hinge 8 present).

Regarding claims 11-17, Eckstein et al. discloses a spacer for providing spacing between an inner surface of the first holding portion and an outer surface of an analyzer; the spacer comprises a plurality of protrusions (10 and 13) projecting from at least one of the inner surfaces of the first and second holding portions; the plurality of protrusions are bendable when an analyzer is inserted into the first holding portion or the second holding portion (plastic material is inherently bendable); the plurality of protrusions include plural kinds of protrusions having different heights; the spacer is formed of an elastic material (plastic is elastic to some degree as it is flexible); the analyzer can be a blood sugar measuring device; and the sampling tool can be a lancing device used for piercing a lancing element into skin.

4. Claims 1-3 and 6-9, 11, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yushiro Chemical Ind. Co., Ltd. (JP 8-233804). Regarding claims 1-3,

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Nobuomi et al. discloses a kit holding adapter designed for holding an analyzer together with a sampling tool; a first holding portion (2) for holding an analyzer and a second holding portion (1) for holding a sampling tool; and the second holding portion includes an opening (top opening in bottom portion 1a) capable of partly exposing an analyzer;

Regarding claims 6-9, 11, 16 and 17, Yushiro Chemical Ind. Co., Ltd. discloses a main body (portion 1a) capable of holding an analyzer and a sampling tool; and an article holding portion (2) capable of containing articles used for at least one of an analyzer and a sampling tool, or other items used in conjunction with the sample analysis or the sampling; the article holding portion includes a plurality of containing rooms (See Fig. 4 embodiment); the article holding portion is removably attached to the main body; a spacer capable of providing spacing between an inner surface of the first holding portion and an outer surface of an analyzer; the analyzer is capable of being a blood sugar measuring device; and the sampling tool is capable of being a lancing device used for piercing a lancing element into skin.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yushiro Chemical Ind. Co., Ltd. (JP 8-233804). Yushiro Chemical Ind. Co., Ltd. discloses the claimed invention except for the specific material that the spacer is made of. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the spacer from any material such as an elastic material in order to have the desired durability. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berke et al. (US 5,100,621), McIvor et al. (US 6,360,888), Wu (US 6,142,298), Kintzig et al. (US 6,379,317), Further (US 4,446,970) and Derr et al. (US 6,068,119).


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q. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Reynolds whose telephone number is (571)272-9959. The examiner can normally be reached on Monday-Friday 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571)272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SAR
March 01, 2007



JILA M. MOHANDESI
PRIMARY EXAMINER